

REMARKS/ARGUMENTS

Claims 1-53 are pending in this patent application. Claims 32-44 are withdrawn. Claims 1-31 and 45-53 currently stand rejected. No claim has been amended. A new claim 54 is added, which is supported at least by paragraph [0089] of the specification of the current application. Accordingly, no new matter has been introduced by this response.

CLAIM REJECTIONS UNDER 35 USC § 103

Claims 1-14, 23/(10) [sic] and 45-52 stand rejected as being obvious over Pourahmadi (US20020055167) or Anderson (US20010036672) in view of Levine (US6031286). Claims 15-22, 23/(17,22) [sic] and 24 are rejected as being obvious over Pourahmadi in view of Levine and further in view of Freeman (US6653124). Claims 25-31 stand rejected as being obvious over Pourahmadi in view of Levine and Freeman and further in view of Kaplan (US6453928) and/or Webster (US6521188). Claim 53 is rejected as being obvious over Pourahmadi in view of Levine and further in view of McDevitt (US20030064422).

These rejections were raised in the previous Office Action and repeated in the current Final Office Action. The Examiner considered Applicants' arguments filed on August 6, 2007 unpersuasive, because:

- (1) Levine teaches in Col. 2, lines 8-14 and in Fig. 4 that it is possible to form a plurality of channels with complex intersections; and
- (2) The combination of Pourahmadi or Anderson with Levine would still be operable even assuming Applicants are correct in stating that Levine is limited in regard to channel complexity.

Applicants have carefully considered the Examiner's reasoning and respectfully disagree, as follows:

Levine Not Enabling For Forming Complex Channels

Col. 2, lines 8-14 of Levine (US6031286) only discloses micropipes arranged in **different layers** and connected by vertical holes that may be made by etching after the formation of the micropipes. There is no indication that micropipes in the **same layer** may be connected to one another or intersect, as in Pourahmadi (US20020055167) or Anderson (US20010036672). More importantly, Levine states that the characteristics of the channel, such as size and shape, are dependent on the aspect ratio of trench and the deposition characteristics of the film being deposited. (Col. 3, lns. 6-10 of Levine.) However, Levine fails to provide any **enabling disclosure** for forming complex channels with crossings or intersections, which are often required in microfluidic devices for biochemical analyses, such as in Pourahmadi or Anderson. See also Declaration Under 37 CFR 1.132 by Mario Scurati (“Declaration”).

It is well settled that a prior art reference must be enabling in order to be used as the basis of a rejection.

The disclosure in an assertedly anticipating reference **must** provide an **enabling disclosure** of the desired subject matter; **mere naming or description of the subject matter is insufficient**, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. ^{*>Mayo Found. For Med. Educ. & Research}*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (At issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation. Without a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art.).

MPEP §2121.01 Use of Prior Art in Rejections Where Operability Is in Question [R-3] (emphases added).

Because Levine contains no enabling disclosure for forming complex channels, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness with respect to the current invention. The Examiner's attention is respectfully directed to *MPEP* §§2141 and 2141.01, updated after the Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), that the *Graham* test should be used in establishing a *prima*

facie case of obviousness (*MPEP* §2141(I)), the first factor of the *Graham* test is to ascertain **the scope and content of the prior art** (*MPEP* §2141(II)), and how to ascertain the scope and content of the prior art (*MPEP* §2141.01 (I) and (II), further citing *MPEP* §§2121-2129 with respect to the “substantive content of the prior art”, including “extent to which prior art must be enabling”).

No Motivation to Combine Because Levine Channels Require Specific Aspect Ratio and Filler Deposition Characteristics Not Found in Pourahmadi or Anderson

Applicants also repeat and maintain their position stated in the response filed August 6, 2007 that there is no motivation for people skilled in the art to consider combining this prior art to reach the current invention. Specifically, Applicants iterate that Levine teaches a technique of filling a pre-formed trench on the surface of a substrate with a filler material. Because the trench is of a specific “aspect ratio” and the filler material is of certain specific “deposition characteristics”, the filler material that lines the upper portions of the sidewalls of the trench meets at a “pinch off point referenced by numeral 30” in Figure 2 of Levine, so that a micro pipe is formed inside the trench. (Col. 3, lns. 1-55, of Levine.)

However, the technique described in Levine is not flexible. It highly depends on the “aspect ratio” of the trench and the “deposition characteristics” of the filler material. Specifically, Levine requires the trench to have a large aspect ratio, which is defined as the ratio of the height (H) of the trench over its width (W). (Col. 3, lns. 40-45, of Levine.) Specifically, the **aspect ratio (H/W) is 2/1**. (Col. 3, lns. 54-55 of Levine.) If a trench does not have such a well-shaped structure, it is highly unlikely that the technique can still form a buried channel in the trench. In one embodiment of the current invention, the channels are approximately 200 μm wide and 150 μm deep, hence with **an aspect ratio (H/W) of 0.75/1**. (Paragraph [0089] of the current application.) See also Declaration. To more specifically point out and claim this feature, a new claim 54 is added to the pending application. No new matter is added by this amendment.

Moreover, Levine only teaches how to form channels of simple shapes (i.e. rectilinear channels in the detailed embodiments of Levine), not complex channels with corners, intersections, ramifications, etc. Based on the teaching of Levine, a person skilled in the art can readily perceive that the “filling” technology described in Levine will probably not function precisely and

predictably when a trench turns, corners, or intersects with another trench. Partial or complete channel occlusion will probably occur. Unpredictable diversions or open-air channels may also occur. All of these are **not** compatible with the manufacturing of microfluidic circuits as described in Pourahmadi or Anderson. See also Declaration. Therefore, one having ordinary skill in the art will **not** regard Levine as a way to modify either Pourahmadi or Anderson. Therefore, there is **no motivation to combine** the references.

No Reasonable Likelihood of Success Because Application of Levine Channels to Complex Channel Shapes of Pourahmadi or Anderson will Probably Fail

Applicants further repeat and maintain their position stated in the response filed August 6, 2007 that there is no reasonable expectation of success to combine Levine with either Pourahmadi or Anderson. Specifically, Applicants re-emphasize that the stringent requirements of channel shape in Levine mean that partial or complete channel occlusion, unpredictable diversions or open-air channels will probably occur when attempting to apply to the complex shapes of the Pourahmadi or Anderson. See also Declaration. Therefore, there is **no reasonable likelihood of success** when combining Levine with Pourahmadi or Anderson, and Applicants respectfully request withdrawal of the obviousness rejections.

DOUBLE PATENTING

Claims 1, 3, 4, 6, and 7 remain provisionally rejected for obviousness-type double patenting over co-pending application 09/874382 (6/4/01). Similarly, claims 1, 3-7 and 10-13 remain rejected over 11/0172,272 (11/20/04), claims 1, 6, 7 are rejected over 11/009171 (10/10/04), and claims 1-3, 5-7, 10-14 and 45-49 are rejected over 11/092415 (03/29/05). Each of these applications was filed after the first US filing date of the current application (09/545,260, filed 4/7/00). Therefore, Applicants maintain their position as stated in the response filed on August 6, 2007 that any rejection based on provisional obviousness-type double patenting should be directed to the later filed application(s), instead of to the current application. Accordingly, Applicants respectfully request withdrawal of the double patenting rejection. However, if deemed absolutely necessary, Applicant may file a terminal disclaimer on notification of allowable subject matter.

CONCLUSION

Applicants have addressed all of the Examiner's rejections. Applicants believe that the claims are now in condition for allowance and respectfully request that the Examiner grant such an action. If any questions or issues remain in the resolution of which the Examiner feels will be advanced by a conference with the Applicants' attorney, the Examiner is invited to contact the attorney at the number noted below. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 50-3420 reference 31175803-004001 (Valoir).

Dated: December 17, 2007

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mario Scurati et al.

Conf. No. 3225

Application No.: 10/663,286

Art Unit: 1744

Filed: September 16, 2003

Examiner: Nathan A. Bowers

For: INTEGRATED DEVICE FOR BIOLOGICAL
ANALYSES

DECLARATION UNDER 37 C.F.R. 1.132

MS After Final
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Mario Scurati, declare as follows:

1. I am at least 18 years of age and am competent in all respects to make the following statements.
2. I am a co-inventor for claims 1-54 currently pending in US Patent Application No. 10/663,286.
3. I have read and understand the above-referenced application and pending claims.
4. I am a person skilled in the art of integrated devices for biological analysis. See the attached *curriculum vitae* (Exhibit I).
5. The present invention is directed to INTEGRATED DLVICE FOR BIOLOGICAL ANALYSES.
6. One prior art cited by the Examiner is Levine (US6031286). I have read and understand Levine.

7. In my view, the technique for making buried channels taught by Levine has some drawbacks that are crucial in microfluidic devices for biochemical analyses.
8. First, the technique of Levine only allows the manufacture of very small micropipes, derived from very narrow trenches with well-defined aspect ratio and deposition conditions. The resulted channels may not be able to receive a sufficient amount of fluid to perform analysis. Trying to make buried channels from wider trenches would cause so high stress that the process could not be exploited. For example, the technique of Levine is not suitable to form 200 μm (wide) by 150 μm (deep) channels as in paragraph [0089] of the current application.
9. Second, the shape and dimension of the cross section of Levine's micropipes are hardly controllable. So, it cannot be predicted how long the fluid will travel through the microfluidic channel in response to operating a pump coupled thereto. In other words, the solution described by Levine is not compatible with precise control of fluid motion and fully automated operation, irrespective of what kind of micropump is used.
10. Hence, the micropipes of Levine are not suitable for use in microfluidic devices for biochemical analyses.

I further declare that all statements made herein of my own knowledge are true and made on information believed to be true; further that these statements were made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of any application for which it is used.

Dated: December 17, 2007

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